

10. REQUEST FOR CONSTRUCTIVE ASSISTANCE

Applicant has made diligent effort to write the claims of this application in allowable condition. If for any reason the claims are not believed to be in full condition for allowance, Applicant respectfully requests the constructive assistance of Examiner pursuant to MPEP 707.07(j), and 706.03(d) in order that this application be placed in allowable condition as soon as possible.

REMARKS

3. TRAVERSE OF REJECTION OF CLAIMS UNDER 35 USC SECTION 112 FIRST PARAGRAPH.

Claim 1 was again rejected because the specification, while being enabling for treating infectious disease caused by a drug-resistant strain of bacteria such as *Staphylococcus aureus* with pepper, does not reasonably provide enablement for treating other infectious diseases caused by other types of drug-resistant strains of bacteria such as *Streptococcus* or *Clostridium difficile* with pepper. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

- 1) The quantity of experimentation necessary
- 2) The amount of direction or guidance provided
- 3) The presence or absence of working examples
- 4) The nature of the invention
- 5) The state of the art
- 6) The relative skill of those in the art
- 7) The predictability of the art and
- 8) The breadth of the claims

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue experimentation in view of further discussion below.

Applicant's regarding the In re Wands analysis is not required are not persuasive since the applicant's instant specification only shows on example for the treatment of a drug-resistant strain bacteria such as *Staph aureus* on page 15, lines 13-31. Again, there are not examples showing other drug-resistant strains of bacteria such as *Streptococcus* or *Clostridium difficile* were eradicated with pepper.

Would a practitioner of the art being of a M.D. administer a drug unknown or does not experimental data showing the drug is effective against certain drug-resistance bacteria to a patient and a successful outcome.

The rejection made under 35 USC 112, first paragraph (Written Description) is adhered to.

This rejection is yet again traversed.

Examiner is incorrect to assert that lack of an actual reduction to practice in treatment of specific infections (Strep, Clostidium ect) precludes enablement.

Applicant refers back to the prior Response F (mailed 10/13/09) pages 4-6, and offers the references below in support of Applicant assertion that the Spec as filed is indeed enabling and properly meets the written description requirement, and fully supports claim 1:

MPEP 2164.02 Working Example – 2100 Patentability

Compliance with the enablement requirement of 35 USC 112, first paragraph, does not turn on whether an example is disclosed. An example may be "working" or "prophetic." A working example is based on work actually performed. A prophetic example describes an embodiment of the invention based on predicted results rather than work actually conducted or results actually achieved.

An applicant need not have actually reduced the invention to practice prior to filing. In *Gould v Quigg*, 822 F. 2d 1074, 1078, 3 USPQ 2d 1302, 1304 (Fed Cir. 1987).

...An invitro or in vivo animal model example in the specification, in effect, constitutes a "working example" if that example "correlates" with a disclosed or claimed method invention.

MPEP 2164.01(b) How to Make the Invention – 2100 Patentability

As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 USC 112 is satisfied. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

21664.01© How to Use the Claimed Invention – 2100 Patentability

If a statement of utility in the specification contains within it a connotation of how to use, and/or the art recognizes that standard modes of administration are known and contemplated, 35 USC 112 is satisfied. *In re Johnson*, 282 F.2d 370, 373, 127 USPQ 216, 219 (CCPA 1960); *In re Hitchings*, 342 F.2d 80, 87, 144 USPQ 637,643 (CCPA 1965) See also *In re Brana*, 51 F.2d 1560, 1566, 34 USPQ 1437, 1441 (Fed. Cir. 1993).

....In other words, if any use is enabled when multiple uses are disclosed, the application is enabling for the claimed invention.

Applicant submits that the written specification is enabling to practitioners of the art to make and use the invention, to ascertain the scope of the invention, that Applicant was in possession of the invention at the time the application was filed, and that all rejections of claim 1 are not proper and should be withdrawn and the claim allowed.

4. TRAVERSE OF REJECTION OF CLAIMS UNDER 35 USC SECTION 112 SECOND PARAGRAPH

Claims 7-22 were rejected as being indefinite for failing to particularly point out, and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 was rejected as indefinite and vague with Applicant leaving out the active agent. Claims 8-22 were rejected as appended to rejected claim 7.

This rejection is traversed.

Claim 7 does indeed list an active agent: "...an antibacterial agent obtainable from solvent extraction of a component of a pepper plant..."

As such, a rejection asserting failure to list an active agent is not proper and should be withdrawn and the claims 7-22 allowed.

Claims 21 & 22 were again rejected as indefinite as lacking antecedent basis with deletion of the phrase "an equivalent" in claim 7 to which they were appended the in the prior amendment.

This rejection is avoided by amendment of claim 7 with reinstatement of the phrase "or an equivalent".

Since claims 21 & 22 now have an antecedent basis in claim 7, rejections as to lack of antecedent basis are not proper and should be withdrawn and the claims allowed.

5. TRAVERSE OF REJECTION OF CLAIM 4 UNDER 35 USC SECTION 102

Claims 4 was again rejected as being anticipated by Gal et. al, or Chen et. al..

This rejection is yet again traversed.

Applicant's traverse in prior Response F (signed and dated 10/13/09) pages 7-9 is here restated, referred to, and adhered to.

In addition, since "phytoalexins" are not mentioned among the above cited references, it is impossible to know to what degree, if any, they may, or may not have been present in the spice/water extracts so tested.

However, since both the above cited references indicate a relatively poor antibacterial performance of the pepper and like spice extracts tested, and fall short of recommending them for medical or veterinary use, it appears likely that if phytoalexins existed at all in the test extracts, they were likely to be in too small a quantity to meet the claim language "...in a therapeutically effective amount." as in claim 4.

Therefore this rejection under 102 in view of Gal et. al, or Chen et. al. is not proper and should be withdrawn and the claims allowed.

The invention as claimed is therefore novel, as the cited references fail to identify all elements of the invention as claimed, and should be withdrawn and the claims allowed.

6. CLAIM AMENDMENTS

Kindly amend claims 1, 4, 5, and 7 to include the phrase "... or an equivalent..." as shown in the CLAIMS below.

Applicant submits that for want of other phraseology, this phrase is necessary to form antecedent basis for dependent claims to more distinctly and more particularly claim the subject of the invention.

Earlier Examiner rejections that assert that this phrase renders the claims indefinite under 35 USC 112 second paragraph are completely unfounded when read in view of the Spec, and not read independently as in a vacuum.

The claims themselves are self explanatory as to what "an equivalent" represents. Example: claims 21 and 22 depend from independent claim 7, and further identify "an equivalent" as ginger or turmeric respectively.

There it is point blank without having to consult the Spec. for clarification.

It was the intent of Applicant to further append claims 21 & 22 to the other independent claims 1, 4, and 5 upon allowance along with others to further define and clarify what constituted "an equivalent" in the claim language itself.

However, this has not as yet happened.

If Examiner would allow the independent claims, Applicant will append dependent claims to more fully identify what "an equivalent" is in the fullest sense in the claim language itself to obviate uncertainty, and appraise the reader of the fullest scope of the claimed invention.

As such, rejections as to claim indefiniteness with the phrase "or an equivalent" is not proper and should be withdrawn, and all the claims allowed.

7. CLAIMS